

AUG 25 1998

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 111-636

LINCOMIX® Soluble Powder
(Lincomycin Hydrochloride)

Sponsored by:

Pharmacia and Upjohn Animal Health.
7000 Portage Road
Kalamazoo, Michigan 49001

Date of Approval: _____

NADA 111-636

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L GENERAL INFORMATION

NADA NUMBER: 111-636

SPONSOR: Pharmacia and Upjohn Animal Health
7000 Portage Road
Kalamazoo, Michigan 49001

ACCEPTED DRUG NAME: lincomycin hydrochloride

TRADE NAME: LINCOMIX[®] Soluble Powder

MARKETING STATUS: Over-the-counter

EFFECT OF SUPPLEMENT: This supplemental approval provides for the assignment of a tolerance of 0.6 ppm for **lincomycin** in swine liver, a tolerance of 0.1 ppm for **lincomycin** in swine muscle, and the assignment of an Acceptable Daily Intake (ADI) of 25 micrograms per kilograms per body weight per day for the total residues of **lincomycin**. In addition, this supplement reduces the slaughter period for drinking water uses of **lincomycin** in swine from 6 days to 0 days.

II. INDICATIONS FOR USE

Swine--For treatment of swine dysentery (bloody scours).

Broiler chickens--For the control of necrotic enteritis caused by *Clostridium prefringens* susceptible to lincomycin.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND RECOMMENDED DOSAGE

As discussed in the Freedom of Information (FOI) Summary for the original approval of NADA 111-636 dated January 28, 1983.

IV. HUMAN SAFETY

A. Toxicity Studies

Toxicity studies conducted for **lincomycin** were described in the FOI Summary for NADA 97-505 dated June 1, 1990.

An ADI of 1.5 mg per 60 kg person per day (equivalent to 0.025 mg/kg body weight per day) was assigned based on procedures described in the *Guideline for Establishing a Safe Concentration* (FR 37499-37500, July 22, 1994) and the CVM document, *Guidance: Microbiological Testing of Antimicrobial Drug Residues in Food* (FDA/CVM, January 1996).

B. Calculations of Safe Concentrations (SC):

Based on the procedures described in the CVM document *Guideline for Establishing a Safe Concentration* dated July 1994, safe concentrations of total residues of lincomycin may be calculated:

$$\text{Safe Concentration (SC)} = \frac{\text{Acceptable Daily Intake (ADI)}}{\text{Consumption Value}}$$

The daily consumption values of edible tissues are approximated as 300 g (0.3 kg) for muscle, 100 g (0.1 kg) for liver, 50 g (0.05 kg) for fat/skin, and 50 g (0.05 kg) for kidney.

$$\text{SC (muscle)} = \frac{1.5 \text{ mg/day}}{0.3 \text{ kg/day}} = 5 \text{ mg/kg} = 5 \text{ ppm in muscle}$$

$$\text{SC (liver)} = \frac{1.5 \text{ mg/day}}{0.1 \text{ kg/day}} = 15 \text{ mg/kg} = 15 \text{ ppm in liver}$$

$$\text{SC (fat/skin)} = \frac{1.5 \text{ mg/day}}{0.05 \text{ kg/day}} = 30 \text{ mg/kg} = 30 \text{ ppm in fat/skin}$$

$$\text{SC (kidney)} = \frac{1.5 \text{ mg/day}}{0.05 \text{ kg/day}} = 30 \text{ mg/kg} = 30 \text{ ppm in kidney}$$

C. Determination of Tolerances

Based on data from studies described in the 1998 FOI Summary for NADA 34-025, a tolerance of 0.6 part per million is established for parent **lincomycin** (marker residue) in the liver (target tissue) of swine. In addition, FDA is retaining the currently codified tolerance of 0.1 ppm for **lincomycin** in muscle.

D. Withdrawal Times

1. Determination of the Residue Decline of **Lincomycin** in the Liver Tissue of Swine Treated with Lincomycin Hydrochloride (U-10149A) at 250 mg of **Lincomycin** Freebase Equivalents per Gallon of Drinking Water
 - a. Report Number: 768-7926-95-005
 - b. Study Completion: February 13, 1996
 - c. Investigator: J.L. Nappier
Pharmacia & Upjohn Company
Kalamazoo, Michigan 49001
 - d. Substance and Dosage Form: Lincomycin was provided in drinking water.
 - e. Species and Strain of Animal: Yorkshire-Hampshire cross swine.
 - f. Number of Animals per Group: Two pigs of each sex per dose per time point (24 total).
 - g. Levels and Duration of Dosing: Medicated water was provided for 7 consecutive days.
 - h. Route of Administration: Orally, via water.
 - i. Parameters: Study parameters included assay of parent **lincomycin** residues in the liver and kidneys of swine at various times after the withdrawal of medicated water. Residue levels were determined by a gas chromatographic method with mass spectrometric detection.

j. Results:

Table 1. Mean levels of parent lincomycin in the livers of swine (ppm) following administration of LINCOMIX® in drinking water for 7 days

Treatment	0 hr	3 hr	6 hr	12hr	24 hr	48 hr
Control	<0.02	-a			.	
250 mg/gal.	-	0.20	0.11	0.05	0.02	<0.02

a. - indicates that samples were not taken at that dose/time point

Mean residue levels were found to be below the tolerance at all time points, even at 3 hours after the final dose.

2. Calculation of Withdrawal Times

Applying its statistical method for determining withdrawal periods to the data sets for lincomycin soluble powder, FDA found that the 99% tolerance limit, with 95% confidence, would be below 0.6 ppm in liver at 4 hours. This statistically derived time permits the assignment of a zero-day withdrawal period for swine treated with lincomycin soluble powder at 250 mg/gallon.

E. Regulatory Method:

Refer to the FOI Summary for NADA 97-505 dated February 25, 1976, for information regarding the regulatory method.

V. AGENCY CONCLUSIONS

Based on the revised consumption values provided in the *Guideline for Establishing a Safe Concentration* (FR 37499-37500, July 22, 1994) and the CVM document, *Guidance: Microbiological Testing of Antimicrobial Drug Residues in Food* (FDA/CVM, January 1996), the Center has established new safe concentrations and tolerances for total residues in edible tissues. The acceptable daily intake (ADI) (25 micrograms per kilograms of body weight per day) and the marker residue tolerance of 0.6 ppm for **lincomycin** in swine liver (target tissue) will be codified under 21 CFR 556.360. In addition, the currently codified tolerance of 0.1 ppm will be retained for **lincomycin** in swine muscle.

In addition, the slaughter withdrawal period for drinking water uses of **lincomycin** in swine has been reduced from 6 days to 0 days. The LIMITATIONS section in 21 CFR 520.1263c will be amended to reflect the 0-day withdrawal period.

According to 21 CFR 514.10f and (xi), this is a Category H supplement. The approval of this change required re-evaluation of the slaughter withdrawal period and the tolerance according to current food safety guidance, but did not require a reevaluation of target animal safety or effectiveness data in the parent application.

The agency has determined under 21 CFR 25.33 (a)(1) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

LINCOMIX® Soluble Powder is not under any unexpired U.S. patents.

VI. APPROVED PRODUCT LABELING

A copy of the draft facsimile labeling is attached to this document.

A. LINCOMIX® Soluble Powder Packet Labels (40 and 80 gram sizes)

B. LINCOMIX® Soluble Powder Carton Labels (40 and 80 gram sizes)

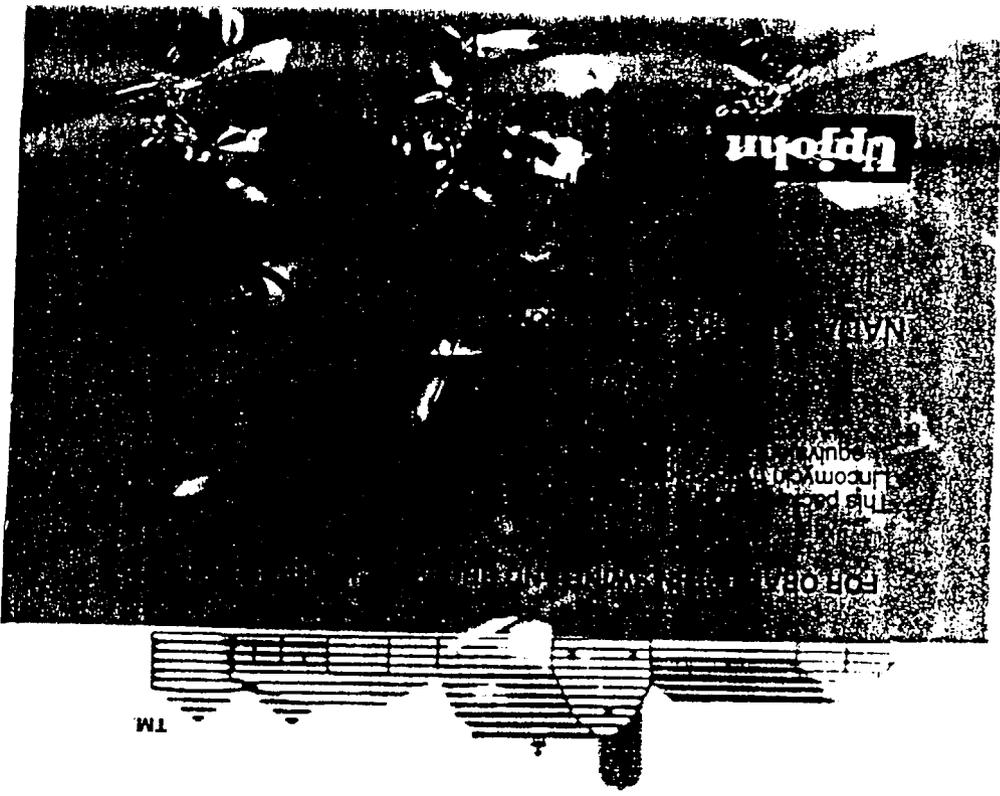
NDC 009-0962-18

LINCOMIX®

Soluble Powder

lincomycin hydrochloride soluble powder

Antibacterial



Restricted Drug—Use Only as Directed (California)

SWINE: Directions for Use

INDICATION: LINCOMIX Soluble Powder is indicated for the treatment of swine dysentery (bloody scours).
DOSEAGE: Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.

TREATMENT PERIOD: The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin premix at 100 grams lincomycin per ton of complete feed as the sole ration according to label directions.

ADMINISTRATION: This packet will medicate 128 gallons of drinking water providing 250 mg/gallon. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water. Pigs are consuming 1.5 gallons of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption. For use in automatic water proportioners, prepare the stock solution by dissolving one packet in one gallon of water; then adjust the proportioner to deliver 1 ounce of stock solution per gallon of drinking water.

NOTE: After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 grams lincomycin per ton of complete feed as the sole ration.

BROILER CHICKENS: Directions for Use

INDICATION: LINCOMIX Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.
DOSEAGE: Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water. Start medication as soon as the diagnosis of necrotic enteritis is determined. If improvement is not noted within 24 to 48 hours, consult a licensed veterinarian. A veterinary diagnostic laboratory to determine diagnosis. The drug should be administered for 7 consecutive days.

ADMINISTRATION: This packet will medicate 500 gallons of drinking water providing 64 mg/gallon.
NOTE: After water medication is discontinued, a control program for necrotic enteritis may be followed by feeding lincomycin premix at 2 grams lincomycin per ton of complete feed.

CAUTIONS

1. Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily. 2. If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis. 3. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, self-correcting within reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment. 4. Do not use in swine weighing more than 250 pounds. 5. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. 6. Do not use the water treatment and the feed treatment simultaneously. 7. Not for use in layer and broiler chickens.

WARNINGS

- 1. Do not slaughter swine for human consumption for 6 days following last treatment.
- 2. No drug withdrawal period is required before slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water.
- 3. Not for human use.

Store in Controlled Room Temperature (59° to 86°F) (15° to 30°C) (59° to 106°F F).
 The Upjohn Company, Kalamazoo, MI 49001, USA

690445

815 934 000

1. No drug withdrawal period is required before slaughter of swine receiving LINCOMIX Soluble Powder at the approved level of 250 mg per gallon of drinking water, nor before slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water.

NDC 0009-096?-7-18

LINCOMIX Soluble Powder

lincomycin hydrochloride

soluble powder



TM

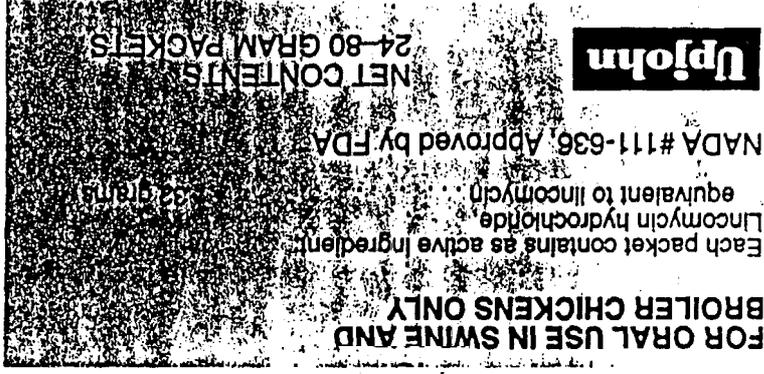
FOR ORAL USE IN SWINE AND BROILER CHICKENS ONLY

Each packet contains as active ingredient lincomycin hydrochloride equivalent to lincomycin

NADA #111-636, Approved by FDA

Upjohn

NET CONTENTS 24-80 GRAM PACKETS



Restricted Drug—Only as Directed (California)

INDICATION: LINCOMIX Soluble Powder is indicated for the treatment of swine dysentery (bloody scours).

INDICATION: LINCOMIX Soluble Powder is indicated for the treatment of swine dysentery (bloody scours). DOSAGE: Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water in clinical studies. This dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.

TRTMENT PERIOD: The drug should be administered for a minimum of 5 consecutive days. If the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin in premix at 100 grams lincomycin per ton or complete feed as the ration according to label directions.

ADMINISTRATION: Each packet will medicate 128 gallons of drinking water providing 5.2 mg/gallon. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when pigs are consuming 1 " s gallons per 100 lbs of body weight per day. Under these circumstances the concentration of lincomycin required in medicated water may be adjusted to compensate for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each or which affects water consumption. For use in automatic water proportioners, prepare the stock solution by dissolving one packet in one gallon of water; then adjust the proportioner to deliver ounce of stock solution per gallon of drinking water.

NOTE: After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 grams lincomycin per ton of complete feed as the ration.

BROILER CHICKENS: Directions for Use INDICATION: LINCOMIX Soluble Powder is indicated for the control of necrotic enteritis caused by Clostridium perfringens susceptible to lincomycin.

DOSE: Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water determined. Improvement is not noted within 24 to 48 hours, consult a licensed veterinarian for veterinary diagnostic laboratory to determine diagnosis. "S". The drug should be administered for 7 consecutive days.

ADMINISTRATION: Each packet will medicate 500 gallons of drinking water providing 64 mg/gallon. NOTE: After water medication is discontinued, a control program for necrotic enteritis may be followed by feeding lincomycin premix at 2 grams lincomycin per ton of complete feed.

CAUTIONS

1. Discard medicated drinking water if not used within 7 days. A fresh stock solution should be prepared daily. 2. If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and redetermine the diagnosis. 3. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment. 4. NOT for use in swine weighing more than 250 pounds. 5. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. 6. Do not use the water treatment and the feed treatment simultaneously. 7. Not for use in layer and breeder chickens.

WARNINGS

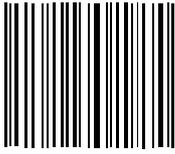
Do not slaughter swine for human consumption for 6 days following last treatment. 2. No drug withdrawal period is required for slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water. 3. Not for human use.

Store at Controlled Room Temperature 15 to 30 C (59 to 86 F)

The Upjohn Company, Kalamazoo, MI 49001, USA 815 923.000

- 1. No drug withdrawal period is required before slaughter of 4 swine receiving LINCOMIX Soluble Powder at the approved level of 250 mg per gallon of drinking water, nor before slaughter of 4 birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water.
- 2. Not for human use.

180 >9ss000



PROOF OF PURCHASE NOT FOR



5031 090962185

NDC 0009-0962-13

LINCOMIX®

Soluble Powder

**lincomycin hydrochloride
(agricultural grade) soluble powder**
Antibacterial



The Department of Health and Human Services
Lincoplant, Inc., a subsidiary of
Lincoplant, Inc., a subsidiary of
Lincoplant, Inc., a subsidiary of

NADA 141-655, Approval Pending

Pharmaceutical
& Supplies

Restricted Drug—Use Only as Directed (California)

SWINE: Directions for Use

INDICATION: LINCOMIX Soluble Powder is indicated for the treatment of swine

DOSE: Administer at a dose rate of 250 mg of lincomycin per gallon of drinking

water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin

per pound of body weight per day.

TREATMENT PERIOD: The drug should be administered for a minimum of 5

consecutive days beyond the disappearance of symptoms (bloody stools) up to a

maximum of 10 consecutive days. If water treatment is discontinued prior to this time,

a lincomycin treatment program may be continued with lincomycin premix at 100 grams

lincomycin per gallon of drinking water according to label directions.

ADMINISTRATION: This packet will medicate 64 gallons of drinking water providing

250 mg/gallon. A dose of 3.8 mg lincomycin per pound of body weight may be

maintained by medicating the drinking water at a concentration of 250 mg per gallon

of drinking water when pigs are consuming 1.5 gallons per 100 lbs of body weight per

day. Under these circumstances the concentration of lincomycin required in medicated

water may be adjusted to compensate for variations in age and weight of animals; the

nature and severity of disease symptoms, environmental temperature and humidity,

each of which affects water consumption.

For use in automatic water proportioners, prepare the stock solution by dissolving two

packets in one gallon of water, then adjust the proportioner to deliver 1 ounce of stock

solution per gallon of drinking water.

NOTE: After a treatment program is discontinued, a control program for swine generally

may be followed by feeding lincomycin premix at 40 grams lincomycin cin per ton of

complete feed as the sole ration.

BROILER CHICKENS: Directions for Use
INDICATION: LINCOMIX Soluble Powder is indicated for the control of the colic infections
caused by *Clostridium perfringens* susceptible to lincomycin.
DOSE: Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water.
TREATMENT PERIOD: Start medication as soon as the diagnosis of colic infections
is determined. Improvement is not noted within 24 to 48 hours, consult a licensed
veterinarian for veterinary diagnostic laboratory. Do not determine diagnosis if the drug should
be administered for 7 consecutive days.
ADMINISTRATION: This packet will medicate 250 gallons of drinking water providing
64 mg/gallon. The control program for swine generally may be followed by feeding lincomycin
premix at 2 grams lincomycin per ton of complete feed.

CAUTIONS: Discard medicated drinking water if not used within 2 days. Fresh stock solution

should be prepared daily. If clinical signs of bloody stools (watery, mucous or bloody

stools) have not improved during the first 5 days of medication, discontinue treatment

and re-determine the diagnosis. Occasionally, swine fed lincomycin may exhibit the

first two days after the onset of treatment develop diarrhea and/or swelling of the anus.

On rare occasions, some pigs may show reddening of the skin and urticaria (hives).

These conditions have been self-correcting within five to eight days without

discontinuing the lincomycin treatment. A Not for use in swine weighing more than 250

pounds. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access

to water containing lincomycin. Ingestion by these species may result in severe

gastrointestinal effects. Do not use the water treatment and the feed treatment

simultaneously. Not for use in layer and broiler chickens.

WARNINGS: Do not elongate swine for the purpose of increasing the amount of medicated

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2. Not for human use.

drinking water.

the approved level of 64 mg per gallon of

of birds receiving LINCOMIX Soluble Powder at

gallon of drinking water, nor before slaughter

Powder at the approved level of 250 mg per

slaughter of swine receiving LINCOMIX Soluble

1. No drug withdrawal period is required before

Store at Controlled Room Temperature 20 to 25° C (68 to 77° F) (see USP)

Pharmacia & Upjohn Company, Kalamazoo, MI 49001, USA. B14 518 005

LINCOMIX Soluble Powder is indicated for the treatment of swine

restricted drug—Use only as directed (California)

swine: Directions for Use

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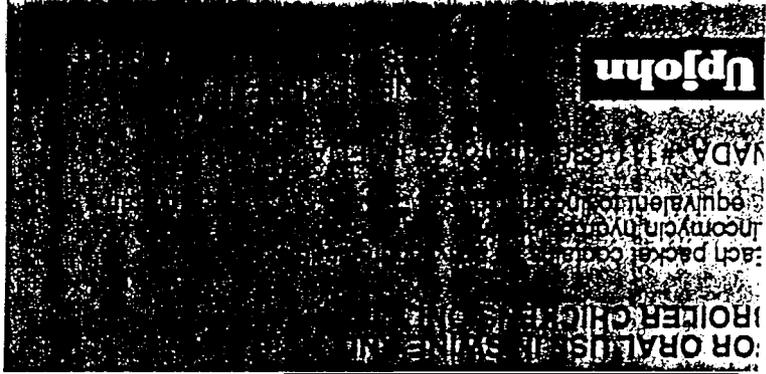
VDC 0009-0967-1 3

LINCOMIX®

Soluble Powder

lincomycin hydrochloride

Antibacterial



Restricted Drug—Use Only as Directed (California)

INDICATION: LINCOMIX Soluble Powder is indicated for the treatment of swine dysentery (bloody scours).

DOSE: Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.

TREATMENT PERIOD: The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days. If water treatment is discontinued prior to this time, a lincomycin treatment program may be continued with lincomycin premix at 100 grams lincomycin per ton of complete feed as the ration according to label directions.

ADMINISTRATION: Each packet will provide 64 gallons of drinking water providing 250 mg of lincomycin per pound of body weight. A dose of 3.8 mg lincomycin per pound of body weight may be maintained by medicating the drinking water at a concentration of 250 mg per gallon of drinking water when circumstances for variations in age and weight of animals, the nature and severity of disease symptoms, environmental temperature and humidity, each of which affects water consumption, are considered. For use in automatic water proportioners, prepare the stock solution by dissolving two packets in one gallon of water; then adjust the proportioner to deliver one ounce of stock solution per gallon of drinking water.

NOTE: After a treatment program is discontinued, a control program for swine dysentery may be followed by feeding lincomycin premix at 40 grams lincomycin per ton of complete feed as the sole ration.

INDICATION: LINCOMIX Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

DOSE: Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water. **TREATMENT PERIOD:** Start medication as soon as the diagnosis of necrotic enteritis is determined. If improvement is not noted within 24 to 48 hours, consult a licensed veterinarian or a veterinary diagnostic laboratory to determine diagnosis. The drug should be administered for 7 consecutive days.

ADMINISTRATION: Each packet will provide 250 gallons of drinking water providing 64 mg/gallon of lincomycin. After water medication is discontinued, a control program for necrotic enteritis may be followed by feeding lincomycin premix at 2 grams lincomycin per ton of complete feed.

CAUTIONS

1. Discard medicated drinking water if not used within 2 days. Fresh stock solution should be prepared daily. 2. If clinical signs of bloody scours (watery, mucoid or bloody stools) have not improved during the first 6 days of medication, discontinue treatment and determine the diagnosis. 3. Occasionally, swine fed lincomycin may within the first two days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, a few pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within five to eight days without discontinuing the lincomycin treatment. 4. Not for use in swine weighing more than 250 pounds. 5. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. 6. Do not use the water treatment and the feed treatment simultaneously. 7. Not for use in layer and breeder chickens.

WARNINGS

1. Do not slaughter swine for human consumption for 5 days following last treatment. 2. No drug withdrawal period is required before slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water. 3. Not for human use.

Store at Controlled Room Temperature 20° to 25° C (68° to 77° F) [see USP].
Pharmacia & Upjohn Company • Kalamazoo, MI 49001, USA
814 632 205

1. No drug withdrawal period is required before slaughter of swine receiving LINCOMIX Soluble Powder at the approved level of 250 mg per gallon of drinking water, nor before slaughter of birds receiving LINCOMIX Soluble Powder at the approved level of 64 mg per gallon of drinking water.

2. Not for human use.

